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HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

JUN - 9 1997

VIA FEDERAL EXPRESS

Byron Economidy
Byron Medical
3280 E. Hemisphere Loop, #100
Tucson, Arizona 85706

Dear Mr. Economidy:

As you are aware from recent conversations with Byron Tart, Director, Promotion and Advertising Policy Staff, Center for Devices and Radiological Health (CDRH), CDRH has reviewed a recent magazine advertisement for Byron Medical's Accelerator™ Aspirator (Accelerator) and your Internet homepage (http://www.byronmedical.com/). The Accelerator, according to you, was cleared by the Food and Drug Administration (FDA) following the submission of premarket notification to FDA pursuant to section 510(k) of the act under the [redacted] The Accelerator is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act. The advertisement and the homepage make inappropriate claims for the aspirator.

The intended use of the aspirator that was cleared in the 510(k) submission [redacted] was as follows, as established in 21 CFR 878.4780. A surgical suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter. The clearance letter from the agency to the 510(k) applicant specifically stated that the device was not intended for use in suction lipectomy.

Byron Medical is not the holder of [redacted] which was submitted by [redacted] in March, 1989. We have reviewed that 510(k) submission and clearance and have concerns that the device that was cleared under [redacted] appears to be physically different from the device in your advertisement. In fact, we question whether the Accelerator II is the same device.

The Accelerator advertisement that we reviewed appears on page 32 of the February/March 1997 issue of "Plastic Surgery Products." The page is entitled "Instruments." The ad claims that "Byron Medical introduces the Accelerator ™ liposuction aspirator. . ." It also says that "the Coleman System for lipostructure is the latest innovation in microinjection products." Whether or not the Accelerator is the same

aspirator as that cleared as [redacted], it is not cleared for use in liposuction. Further, we are unable to find in FDA's records any mention of the "Coleman System," but in any case, there has been no product cleared for "lipostructure."

Byron Medical's Internet page that we reviewed was entitled, "Liposuction" and includes a discussion of the Accelerator II and a list of numerous cannulae to be ordered and used with the device.

The claims for liposuction and lipoculpture have misbranded and adulterated, within the meanings of sections 502(o) and 501(f)(1)(B) of the Act, respectively, the Accelerator aspirator as well as each of the cannulae and the Coleman System. Each of the products is misbranded because a notice or other information respecting the device was not provided to the FDA as required by section 510(k) and none of them has been found to be substantially equivalent to a predicate device for the uses claimed. The devices are adulterated because they are class III devices under section 513(f) and do not have approved applications for premarket approval in effect pursuant to section 515(a) or approved application for investigational device exemptions under section 520(g). The aspirator may be further misbranded under section 502(o) if notice or other information respecting a modification to the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(i) if the substantial apparent physical differences between your device and the cleared device constitute a modification to the device that could significantly affect the safety or effectiveness of the device, i.e., a significant change or modification is design.

FDA's regulations at 21 CFR 801.4 provide that the term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. That intent may be shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. Making claims regarding liposuction and lipostructure impermissibly changes the intended use of the device. Pursuant to section 510(k) of the act and as provided in 21 CFR 807.81(a)(3)(ii), claims that state or imply that the devices can be used for liposuction, lipostructure or any other procedure that means the removal or distribution of fat tissue require the submission to FDA of premarket notification.

As further provided in 21 CFR 801.4, you may change the intended use of, and therefore misbrand and adulterate, products not manufactured by you if you advertise or promote them for a use different from that intended by the person from whom you received them. It is unclear whether all of the products are manufactured by you, but as a distributor, you are responsible for marketing the devices in a manner consistent with the intended use cleared for the product or for providing adequate labeling for new intended uses of the device.

This letter is not intended to be an all-inclusive list of deficiencies associated with the Aspirator, the cannulae and the Coleman system. The specific violations in this letter may represent practices used in other promotional or advertising materials used by your firm.

You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunctions and/or civil penalties.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should include steps being taken to address misleading information currently in the marketplace and actions to prevent similar violations in the future. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Send your response to Deborah Wolf, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Los Angeles District Office (HFR-PA240), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92715.

Sincerely,

Byron Tart for

Lillian Gill
Director
Office of Compliance
Center for Devices and
Radiological Health